

Attorney Docket No.: **KBI-0015**
Inventors: **Ranganathan, Natarajan**
Serial No.: **10/689,359**
Filing Date: **October 20, 2003**
Page 6

REMARKS

Claims 1-11 are pending in the instant application. Claims 1-11 have been rejected. No new matter has been added by this amendment. Reconsideration is respectfully requested in light of the following remarks.

I. Rejection of Claims Under 35 U.S.C. §103

Claims 1-3 and 6 remain rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,902,578 (Halpin-Dohnalek et al.).

Claims 1, 3-6 and 8 remain rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,085,874 (Jungvid).

Claims 1, 3-5, 7, 9 and 10 remain rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,744,134 (Paul).

Claims 1-5, 7, 10 and 11 have been rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,518,740 (Costanzo et al.).

It is suggested that the cited references teach the compositions of the instant invention for use in maintaining GI health and restoring GI health. It is suggested that while the cited references do not teach the specific amounts of each component as recited in the claims or a water content of less than about 0.47, a person of ordinary skill would have a reasonable expectation of success in making the compositions of the referenced teachings with the instant recited amounts because the cited references teach that the composition of their mixture can be varied and powdered compositions. The Examiner suggests that it would have been routine in the art to optimize the

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Serial No.: **10/689,359**
Filing Date: **October 20, 2003**
Page 7

amounts of each component and water content of the referenced compositions with a reasonable expectation of successfully obtaining the reference composition. Applicant respectfully traverses these rejections.

At the outset, Applicant respectfully points out that the instant claims do not recite water content or residual moisture, rather the claims disclose a particular water activity for the claimed nutritional food or nutritional product. The water activity of a composition is not the same thing as its water content. Water in a composition can be bound or unbound to molecules of the composition. The term water activity refers to the unbound water. As such, while two compositions may have exactly the same water content, they can have quite different water activities. This occurs because a portion of the total water content present in a composition is bound to specific sites on the molecules of the composition. These sites may include the hydroxyl groups of carbohydrates, the carbonyl and amino groups of proteins, and other polar sites such as on edible fats. Thus, ingredients of the instant foods and their respective amounts are important to achieving the claimed water activity and, as disclosed in the specification, delivery of viable bacteria at particular doses.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success.

Attorney Docket No.: **KBI-0015**
Inventors: **Ranganathan, Natarajan**
Serial No.: **10/689,359**
Filing Date: **October 20, 2003**
Page 8

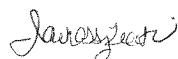
Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. MPEP 2142.

While the cited references teach powders and Costanzo et al. teach residual moisture amounts, there is no teaching or suggestion of the water activity of the powders or the impact of food ingredients on water activity. Thus, it simply would not have been obvious at the time of the claimed invention to optimize the referenced ingredients to achieve a water activity of less than about 0.47 to provide 5 billion to 20 billion cfu of viable bacteria, as there is no teaching, suggestion or motivation in the referenced teachings for doing so. Therefore, these references cannot be held to make the present invention obvious under 35 U.S.C. 103(a). Accordingly, it is respectfully requested that these rejections be reconsidered and withdrawn.

II. Conclusion

The Applicant believes that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,



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